



## EU Declaration of Conformity

Heidenheim, 2025-11-20

<b>Product Group Number</b>	<b>2022</b>
<b>Manufacturer</b>	PAUL HARTMANN AG Paul-Hartmann-Str. 12 89522 Heidenheim GERMANY

We herewith declare under our sole responsibility that the product listed above, first placed on the market by PAUL HARTMANN AG, satisfies the applicable provisions of the following listed legislations. The conformity assessment procedures have been performed and the Technical Documentation is kept available.

### Applied legislative acts

#### Medical Device Regulation (EU) 2017/745

High Level Intended Purpose	General single-use, non-active, non-implantable devices used in health care	
Classification	<b>Risk Class</b>	<b>Rule</b>
	I s	Rule 1
Conformity Assessment Procedure	Article 52 (7) and Annex XI part A with respect to sterility	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Production Quality Assurance Certificate No. G26 011858 0077 Rev. 00,  Device Group: T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002022JQ	

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück  
 (Vorsitzende des Vorstands/CEO), François Georgelin,  
 Stefan Grote, Oliver Neubrand  
 Aufsichtsratsvorsitzender/Chairman of the Supervisory Board:  
 Fritz-Jürgen Heckmann

Sitz Heidenheim  
 Amtsgericht Ulm HRB 661090  
 Registered Office Heidenheim  
 Commercial Register of the District Court of Ulm file no. HRB 661090

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P.O. Box 1420  
89504 Heidenheim  
Germany



Helps. Cares. Protects.

Product Group Number	2022	
	Code	Term
EMDN	T0202	SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)
GMDN	47783	Patient surgical drape, single-use, sterile
UMDNS	15-646	Drapes, Surgical, Disposable

PAUL HARTMANN AG

ppa.

**Martin Walther**  
Senior Vice President  
Risk Prevention

i.V

**Christiana Hofmann**  
Head of Regulatory Affairs, PRRC  
Risk Prevention

**Valid from:** 2025-11-30

**Valid until:** 2030-11-29

GLN 404 9500 00000 0

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List of products falling under the respective Product Group Number:

**2022**

<b>REF</b>	<b>Name - Description</b>
936763	Foliodrape Protect Plus Thorax set II
938742	Foliodrape Protect Plus Cardiovascular set
936764	Foliodrape Protect Plus Thorax set I, crepe
938827	Foliodrape Protect Plus Chest drape

GLN 404 9500 00000 0

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